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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,985	03/19/2004	Sylvia Daunert	50229-430	6910

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
01/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,985	Applicant(s) DAUNERT ET AL.	
	Examiner Raymond J. Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/05/07
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 6 and 7 is/are allowed.
- 6) ☒ Claim(s) 3 and 9-20 is/are rejected.
- 7) ☒ Claim(s) 4, 5, 8, 16 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/8/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-20 ARE PRESENTED FOR EXAMINATION

Applicants' response filed November 5, 2007 and Preliminary Amendment filed March 19, 2004 have been received and entered into the application.

Accordingly, the specification at page 1 has been amended as indicated by Applicants.

Restriction Requirement

Upon reconsideration, the requirement for restriction set forth in the previous Office action dated October 3, 2007 is withdrawn. This decision is made because upon a search of the appropriate data bases, the subject matter claimed in present claims 1-20 is of sufficient scope for the Examiner to consider all such subject matter without an undue burden. Applicants' remarks in their response which are responsive to the restriction requirement are rendered moot.

Accordingly, claims 1-20 are herein acted on the merits.

Claims Allowable

Present claims 1, 2, 6 and 7 are directed to an electroactive hydrogel comprising (i) acrylamide; (ii) an unsaturated aliphatic acid; (iii) a conductive polymer; and (iv) a cross-linking agent. The Examiner finds that (i) claims 1, 2, 6 and 7 conform to the standards under 35 U.S.C. § 112, first and second paragraphs and (ii) there is no reference available as prior art which teaches or would have suggested the subject matter of these claims.

Accordingly, these claims are deemed to be in condition for allowance.

The remaining claims, claims 3-5 and 8-20, are subject to formal rejections/objections as detailed below. As with claims 1, 2, 6 and 7, the Examiner has found no reference available as prior art which teaches or would have suggested the subject matter of the remaining claims.

Claim Objections

Claims 4-5 are objected to as depending from a rejected base claim, but are otherwise in condition for allowance.

Claims 8, 16 and 18 are objected to because it does not appear that they are directed to subject matter which further limits the subject matter of the claims from which they depend.

In particular, in claims 8 and 16 "bisacrylamide" and in claim 18 "methylenebisacrylamide", have not been identified as being a species of (i) unsaturated aliphatic acid; (ii) conductive polymer; or (iii) at least one cross-linking agent and thus do not appear to be further limiting. It is noted that the base claims also provide for "acrylamide". However, because it is not preceded by the article "an", the base claims only provide for the chemical entity known as acrylamide, (i.e., prop-2-enamide).

If the compounds of claims 8, 16 and 18 are compounds present in addition to the compounds of the base claims, these claims should then be amended to read "wherein the hydrogel/composition *further* comprises...", as suitable for each claim.

If the compounds are indeed species of those elements present in the base claim, then the claims should be amended to identify the compounds appropriately, e.g., "wherein the hydrogel comprises about 20 wt.% bisacrylamide as the cross-linking agent, (claim 8).

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an electroactive hydrogel composition or a drug delivery device which contains a therapeutic or diagnostic agent, or a method of delivering a therapeutic or diagnostic agent by employing such device, does not reasonably provide enablement for such composition or device which contains a "prophylactic" agent or such method where a "prophylactic" agent is delivered.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that a "prophylactic agent" may be present or delivered in the manner herein claimed is doubted because the art does not recognize that absolute prophylaxis or prevention of a disease, such that the disease is kept from manifesting to *any degree* can be accomplished with a reasonable degree of certainty.

The term “prophylactic agent” may be reasonably interpreted as being synonymous with an agent capable of “curing” a disease which circumscribes instances of absolute success. Because the art does not recognize absolute success as a reasonable possibility with the vast majority of diseases, especially those having an etiology and pathophysiological manifestations which are complex/poorly understood, one skilled in the art would require a substantial, objective and rigorous showing to establish that Applicants have indeed identified “prophylactic agents” for use in their invention. Lacking such a showing and thus an enabling disclosure, one skilled in the art could not practice the claimed invention with a reasonable expectation of accomplishing the objectives disclosed and claimed by Applicants.

The Examiner notes that the term “prophylactic” or “prophylaxis” not *necessarily* synonymous with a “cure”. However, such interpretation is clearly proper given that “During patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’ *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicants always have the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969).” (MPEP § 2111).

Accordingly, for the above reasons, the claims are deemed properly rejected as containing subject matter that has not been enabled such that one skilled in the art could practice the invention with a reasonable expectation of success.

Overcoming This Rejection

In order to overcome this rejection, Applicants may wish to consider deleting instances of “, prophylactic” or “prophylactic” from the appropriate claims.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 14-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.”, (see MPEP § 2173).

In the above claims, the intended limiting effect of the expressions "most preferably" and "preferably" is not clear and such terms have not been defined in the present specification such that one would be apprised of Applicants' intent in employing these expressions.

Overcoming This Rejection

Applicants may wish to delete the expressions "most preferably" and "preferably" in order to overcome the present rejection.

Accordingly, for the above reasons, the claims are deemed properly rejected as being indefinite.

Application/Control Number:
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Art Unit: 1614

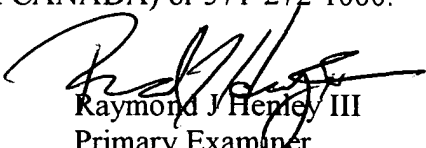
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For the reasons set forth above the claims subject to rejection of objection are currently not in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Raymond J Henley III
Primary Examiner
Art Unit 1614

January 19, 2008